526 Rec'd PCT/PTO 06 JUL 2001

FORM PTO-1390 U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 4139-120

U S APPLICATION NO (If known, see 37 CFR 1 5): 09/889003

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DE00/00038	05 January 2000	08 January 1999

TITLE OF INVENTION

METHOD AND DEVICE FOR DETERMINING VOLUMES IN THE HUMAN OR ANIMAL BODY

APPLICANT(S) FOR DO/EO/US

Andreas Mahr, Malte Bahner and Sabine Levegrun

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau)
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).

6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.

8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).***(Unsigned)**

10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S C 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification.

15. ☒ A small entity statement.

16. ☒ Other items or information: EPO Search Report

NOTE: This application is being filed with an unsigned Oath or Declaration under the provisions of 37 CFR § 1.53 in order that applicants may secure a filing date of July 6, 2001. Upon receipt of a "Notice to File Missing Parts - Filing Date Granted," a Declaration and Power of Attorney will be filed in the Patent and Trademark Office. The undersigned agent affirmatively states that she has been duly authorized and appointed to file this application on behalf of the applicants and applicants' assignees, and that the Declaration and Power of Attorney to be filed hereafter will confirm the undersigned agent's authorization and appointment. Applicants are a small entity within the meaning of 37 CFR § 1.9.

09/889003

532 Rec'd PCT/PTO 06 JUL 2001

17. ☒ The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5)): Search Report has been prepared by the EPO or JPO ....$860.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) ....$0.00 No International preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) ....$0.00 Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO ....$1000.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $0.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	20-20 =	0	X **$18.00**	$	
Independent Claims	2- 3 =	0	X **$80.00**	$	
Multiple dependent claim(s) (if applicable)			+ **$270.00**	$	

TOTAL OF ABOVE CALCULATIONS =	860.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).	$ 430.00	
SUBTOTAL =	$ 430.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 Months from the earliest claimed priority date (37 CFR 1.492(f)). +	$	
TOTAL NATIONAL FEE =	$ 430.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +	$	
TOTAL FEE ENCLOSED =	$ 430.00	
	Amount to be: refunded	$
	Charged	$

a. ☒ A check in the amount of $430.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _______ in the amount of $_______ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 08-3284. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not yet been met, a petition to revive (37 CFR 1.127(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Steven J. Hultquist
Intellectual Property/Technology Law
P. O. Box 14329
Research Triangle Park, NC 27709

MARIANNE FUIERER
Registration No. 39,983

09/889003

Rec'd PCT/PTO 06 JUL 2001

23448

PATENT TRADEMARK OFFICE

4139-120

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Andreas Mahr, et al.**
Application No.:	New U.S. National Stage Application of PCT International Application No. PCT/DE00/00038
International Filing Date:	05 January 2000
Priority Date Claimed:	08 January 1999 (German Appl. No. 199 00 414.5)
U.S. National Phase Filing Date:	Date of mailing identified below
Title:	**METHOD AND DEVICE FOR DETERMINING VOLUMES IN THE HUMAN OR ANIMAL BODY**

EXPRESS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Commissioner for Patents, Box Patent Application, Washington, DC 20231, and Express Mailed under the provisions of 37 CFR 1 10

Lee Ann Brown

Name of Person Mailing This Document

Lee Ann Brown

Signature

July 6, 2001

Date

EL666414211US

Express Mail Label Number

PRELIMINARY AMENDMENT

Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified new national phase patent application, please amend the application, as follows:

In the Claims

Please amend claims 1-20 to read as follows:

1. A method for determining a volume in a human or animal body, wherein image data of an imaged volume are acquired by means of a suitable imaging method and the acquired image data are segmented in a manual, semi-automated or fully automated fashion, and wherein dimensional information on the imaged volume is automatically determined from the segmented image data, the method comprising:

assigning to the steps in which the image data is acquired and segmented at least one previously determined characteristic value, with said characteristic value representing a measure for an error occurring in these steps, wherein an error value represents a measure for the error occurring in the determination of the dimensional information related to the assigned characteristic value, and wherein the error value is displayed or output, respectively together with the assigned dimensional information.

2. The method according to Claim 1, wherein the at least one characteristic value is also assigned to the imaged volume and taken into consideration when determining the error value of the dimensional information.

3. The method according to Claim 1, wherein the segmenting process is carried out in a manual or semi-automated fashion and at least one personal characteristic value is assigned to each person carrying out the method and taken into consideration when determining the error value of the dimensional information.

4. The method according to Claim 3, wherein the personal characteristic value assigned to each person is determined automatically.

5. The method according to Claim 4, wherein the automatic determination of the characteristic value assigned to a person is realized based on a manual or semi-

automated segmenting process which is carried out by the respective person with predetermined test data.

6. The method according to Claim 1, wherein the at least one characteristic value assigned to the step in which the image data is acquired contains at least one measure selected from the group consisting of signal-to-noise ratio, tissue contrast, pitch, increment, sequence parameters, layer thickness, matrix size, and filter used.

7. The method according to Claim 1, wherein at least one characteristic value assigned to the step in which the segmenting is performed contains a measure for the accuracy of a segmenting method used for the segmenting process and/or a measure for the reproducibility of the results of the segmenting method used.

8. The method according to Claim 2, wherein the at least one characteristic value assigned to the interesting volume contains a measure for the size and/or the shape of the interesting volume.

9. The method according to Claim 1, wherein the interesting volume consists of the volume of a tumor.

10. The method according to Claim 1, the interesting volume consists of the volume of an organ.

11. A device for determining a volume in a human or animal body, comprising:
means for inputting image data of an imaged volume;
means for segmenting the image data in a manual, semi-automated or fully automated fashion;
means for automatically determining dimensional information of the imaged volume from the segmented image data; and
at least one data memory for storing at least one characteristic value which can be assigned to the input and/or the segmented image data in accordance with predetermined criteria, wherein the means for automatically determining the dimensional information is coupled to the at least one data memory and designed

such that they are able to read the at least one characteristic value out of the data memory and determine an error value for the characteristic value which represents a measure for the error occurring in the determination of the dimensional information.

12. The device according to Claim 11, wherein the characteristic value which is assigned to the imaged volume is stored in the data memory.

13. The device according to Claim 11, further comprising means for displaying and/or outputting the determined dimensional information and the determined error value and coupled to the means for automatically determining the dimensional information.

14. The device according to Claim 11, wherein a characteristic value for each person operating the device is stored in at least one data memory that is coupled with the means for automatically determining the dimensional information.

15. The device according to Claim 14, wherein the data memory contains stored test data records, wherein the person operating the device is able to carry out a manual or semi-automated test segmenting process on said test data records.

16. The device according to Claim 15, further comprising means for evaluating the test segmenting process and means for determining and storing a personal characteristic value for the respective person.

17. The device according to Claim 16, wherein a data record is assigned to the personal characteristic value, wherein said data record identifies the test data record/test data records used for determining the respective characteristic value.

18. A medical imaging apparatus with a device according to Claim 11.

19. The medical imaging apparatus according to Claim 18 wherein the apparatus is used for determining the volume of a tumor.

20. The medical imaging apparatus according to Claim 18 wherein the apparatus is used for determining the volume of an organ.

REMARKS

A marked-up version of amended claims 1-20 is included herewith in Appendix A.

It is requested that the examination and prosecution of this application proceed on the basis of the English translation of the PCT International application included herewith and these amended claims 1-20.

Respectfully submitted,

Marianne Fuierer
Registration No. 39,983
Attorney for Applicants

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
P. O. Box 14329
Research Triangle Park, NC 27709
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File: 4139-120

APPENDIX A

1. A method for determining a volume[s] in a human [bodies or] animal body [bodies], wherein image data of an imaged [interesting] volume are acquired by means of a suitable imaging method and the acquired image data are segmented in a manual, semi-automated or fully automated fashion, and wherein dimensional information on the imaged [interesting] volume is automatically determined from the segmented image data, the method comprising: [characterized by the fact]

assigning [that at least one previously determined characteristic value is assigned] to the steps in which the image data is acquired and segmented at least one previously determined characteristic value, with said characteristic value representing a measure for [the] an error occurring in these steps, wherein an error value [by the fact

that an error which] represents a measure for the error occurring in the determination of the dimensional information related to [is determined from] the assigned characteristic value, and wherein [by the fact

that] the error value is displayed or output, respectively[, preferably] together with the assigned dimensional information.

2. The method according to Claim 1, wherein the [characterized by the fact that] at least one characteristic value is also assigned to the imaged [interesting] volume and taken into consideration when determining the error value of the dimensional information.

3. The method according to Claim 1[or 2], wherein the segmenting process is carried out in a manual or semi-automated fashion and [, characterized by the fact that]at least one personal characteristic value is assigned to each person carrying out the method and taken into consideration when determining the error value of the dimensional information.

4. The method according to Claim 3, wherein [characterized by the fact that] the personal characteristic value assigned to each person is determined automatically.

5. The method according to Claim 4, wherein [characterized by the fact that] the automatic determination of the characteristic value assigned to a person is realized based on a manual or semi-automated segmenting process which is carried out by the respective person with predetermined test data.

6. The method according to Claim 1, [one of Claims 1 - 5, characterized by the fact that] wherein the at least one characteristic value assigned to the step in which the image data is acquired contains at least one measure selected from the [following] group consisting of [measures:] signal-to-noise ratio, tissue contrast, pitch, increment, sequence parameters, layer thickness, matrix size, and filter used.

7. The method according to Claim 1 [one of Claims 1 - 6], wherein [a semi-automated or automated segmenting process is carried out , characterized by the fact that the] at least one characteristic value assigned to the step in which the segmenting is performed [carried out] contains a measure for the accuracy of a segmenting method used for the segmenting process and/or a measure for the reproducibility of the results of the segmenting method used.

8. The method according to Claim 2, wherein [characterized by the fact that] the at least one characteristic value assigned to the interesting volume contains a measure for the size and/or the shape of the interesting volume.

9. The method according to Claim 1, [one of Claims 1 - 8,] wherein [characterized by the fact that] the interesting volume consists of the volume of a tumor.

10. The method according to Claim 1, [one of Claims 1 - 8, characterized by the fact that] the interesting volume consists of the volume of an organ.

11. A device for determining a volume[s] in a human [bodies] or animal body [bodies], comprising:

[with] means for inputting image data of an imaged [interesting] volume; [, with]

means for segmenting the image data in a manual, semi-automated or fully automated fashion; [, and with]

means for automatically determining dimensional information of [on] the imaged [interesting] volume from the segmented image data; and [characterized by the fact]

[that] at least one data memory [is provided, by the fact] for storing [that] at least one characteristic value[s] which can be assigned to the input and/or the segmented image data in accordance with predetermined criteria, wherein the [are stored in the at least one data memory, and by the fact

that the] means for automatically determining the dimensional information is [are] coupled to the at least one data memory and designed such

that they are able to read the at least one characteristic value[s] out of the data memory and determine an error value for [from] the characteristic value[s] which represents a measure for the error occurring in the determination of the dimensional information.

12. The device according to Claim 11, wherein [characterized by the fact that a] the characteristic value which is assigned to the imaged [interesting] volume is stored in the data memory.

13. The device according to Claim 11 [or 12], further comprising [characterized by the fact that] means [are provided] for displaying and/or outputting the determined dimensional information and the determined error value and coupled to the means for automatically determining the dimensional information.

14. The device according to Claim 11, [one of Claims 11 - 13, characterized by the fact that] wherein a characteristic value[s] for each person operating the device is [are]

stored in at least one data memory that is coupled with the means for automatically determining the dimensional information.

15. The device according to Claim 14, wherein [characterized by the fact that a] the data memory contains stored [with] test data records [is provided], wherein the person operating the device is able to carry out a manual or semi-automated test segmenting process on said test data records.

16. The device according to Claim 15, further comprising [characterized by the fact that] means [are provided] for evaluating the test segmenting process and [, as well as for] means for determining and storing a personal characteristic value for the respective person.

17. The device according to Claim 16, wherein [characterized by the fact that] a data record is assigned to the personal characteristic value[s], wherein said data record identifies the test data record/test data records used for determining the respective characteristic value.

18. A medical imaging apparatus with a device according to Claim 11 [one of Claims 11 - 17].

19. The medical imaging apparatus according to Claim 18 wherein the apparatus is used [A utilization of a device or a medical apparatus according to one of Claims 11 - 18] for determining the volume of a tumor.

20. The medical imaging apparatus according to Claim 18 wherein the apparatus is used [The utilization of a device or medical apparatus according to one of Claims 11 - 18] for determining the volume of an organ.

METHOD AND DEVICE FOR DETERMINING VOLUMES IN THE HUMAN OR ANIMAL BODY

The invention pertains to a method and a device for determining volumes in human bodies or animal bodies. In this case, image data of an interesting volume are acquired by means of a suitable imaging method and subjected to a manual, semi-automated or fully automated segmenting process. Dimensional information on the interesting volume is then automatically determined from the segmented image data.

Such methods and devices are known in various forms. They provide information that, among other things, is used by physicians, e.g., in the diagnosis of tumors, in choosing the appropriate therapy and in monitoring the progress of the therapy, as well as in organ transplants.

The known methods and devices proved quite effective in practical applications, with particular advances having been achieved in semi-automated and the fully automated segmenting processes in recent years. In this respect, the term "segmenting" refers to the process called "image comprehension," namely the transition of a certain quantity of pixels of a plurality of pixels (or - in volume data records - voxels) into a symbolic description (tumor, bones, etc.). Such a segmenting process is composed of a classification, namely the formation of equivalence classes in the characteristic space, and an identification, i.e., an inverse transformation of the elements of an equivalence class from the characteristic space into the local space.

The invention is based on the objective of disclosing a method and a device for determining volumes in human bodies or animal bodies, in which the accuracy of the determined values and the ability to interpret said values is significantly improved in comparison to known methods and

devices. In addition, it should be possible to easily utilize the new method and the new device in combination with or as a retrofitting option for known methods and devices.

The first aspect of this objective is attained with a method of the initially described type, in which at least one characteristic value is assigned to the steps in which the image data is acquired and segmented, with the characteristic value representing a measure for the error occurring in these steps, and in which an error value is determined from the assigned characteristic value in the form of a measure for the error occurring in the determination of the dimensional information, with the error value being displayed or output, respectively. It is preferred that the error value can be assigned to the dimensional information such that these two values can be archived in a correlated fashion.

It would also be possible to respectively assign at least one characteristic value that respectively represents a measure for the errors occurring in the respective step to the steps in which the image data are acquired and segmented. These characteristic values can then be linked to form a characteristic value and used in this fashion or used separately.

Known methods and devices frequently give the user the wrong impression that the obtained values are absolutely accurate because error limits are not indicated. This can have fatal consequences, in particular, with respect to the fact that the users of such methods usually are highly stressed physicians who are unable to evaluate which inaccuracies caused, in particular, due to physical circumstances are incorporated into the final value at which point of the determination process. In addition, a fast decision in interpreting the data delivered by known

methods and devices is necessary for cost reasons. For example, it may occur that, during the monitoring of the therapy progress, the volume of a tumor is initially determined to be 50 ml, then 48 ml and ultimately 43 ml with a known method. This apparently indicates that the therapy is effective. Due to technical, physical or biological peculiarities, the inaccuracy of the measurement may actually differ and, for example, amount to +/- 2 ml in the first measurement, +/- 4 ml in the second measurement and +/-7 ml in the third measurement. This means that the actual volume of the tumor may have been only 48 ml in the first measurement and 49 ml in the last measurement. This indicates that the chosen therapy, e.g., chemotherapy, is not effective and that another type of therapy, e.g., radiation therapy, should be started as soon as possible.

The method according to the invention increases the accuracy of the thusly determined data significantly. If the method is, for example, used in the field of medicine, in particular, tumor medicine, the treating physician is able to evaluate the volume information that is essential for deciding on the corresponding therapy and for monitoring the progress of the therapy in a significantly more differentiated fashion since it is now possible to indicate error limits. The decision process is significantly simplified for the physician, and the physician does not require detailed information on the usually very complicated technique and its physical aspects.

The method provides the additional advantage that it can be utilized in all types of imaging methods, e.g., CT, MRT, PET, ultrasound, etc. In this respect, it is merely required to adapt the parameter or the parameters that are dependent on the respective method. Depending on the type of imaging method used, the at least one characteristic value assigned to the step in which the image data is

acquired usually contains at least one measure of the following group of measures: signal-to-noise ratio (e.g., influenced by the tube voltage, the tube current or the reconstruction kernels), tissue contrast, pitch and/or increment (in spiral-CT), sequence parameters (in MRT), layer thickness, matrix size and/or filter used.

If a semi-automated or fully automated segmenting process is carried out, the at least one characteristic value assigned to the segmenting step may contain a measure for the accuracy of a segmenting method used in the segmenting process and/or a measure for the reproducibility of the results of the segmenting method used.

However, if a manual or semi-automated segmenting process is carried out, it is preferred to assign a personal characteristic value to each person carrying out the method, and to take this personal characteristic value into consideration in determining the error value of the dimensional information. This advantageously makes it possible to incorporate the different segmenting capabilities of the persons carrying out the method into the determination of the error value, i.e., it can be taken into consideration that the accuracy of volumes determined from image data records which were segmented by a skilled person is higher than the accuracy of volumes determined from image data records which were segmented by unskilled persons.

In this case, the personal characteristic value assigned to each person can be automatically determined, e.g., by having the respective persons carry out one or more manual or semi-automated segmenting process(es) with predetermined test data. A self-learning system can be realized in this fashion. In this respect, it may be advantageous if the operating personnel carries out segmenting processes with test data within regular or irregular intervals.

Fluctuations in the performance of the individual operators which may depend on their shape on the day in question or the like can be detected by segmenting respectively identical test data. In order to determine learning effects, respectively different test data may be used for determining the personal characteristic value. It goes without saying that both aforementioned methods may also be used cumulatively, i.e., part of the test data is repeatedly segmented and another part is presented to the operator much less frequently. The former part makes it possible to determine, for example, an error bandwidth, and the latter part of the test data provides information, for example, on learning effects.

In one advantageous variation of this method, at least one characteristic value is assigned to the interesting volume and taken into consideration in determining the error value of the dimensional information. Depending on the type of structure contained in the interesting volume, e.g., a tumor or an organ, its size and/or shape, for example, play a different role in the determination of the accuracy and the error interval of the volume value.

The second aspect of the aforementioned objective is attained with a device for determining volumes in human bodies or animal bodies which contains means for inputting image data of an interesting volume, means for segmenting the image data in a manual, semi-automated or fully automated fashion and means for automatically determining dimensional information on the interesting volume from the segmented image data, wherein said device is equipped with at least one data memory, in which characteristic values are stored that can be assigned to the input data and/or the segmented image data in accordance with predetermined criteria, and wherein the means for automatically determining the dimensional information are coupled to the at least one data memory and realized in such a way that

they are able to read the characteristic values out of the data memory and determine an error value in the form of a measure for the error occurring in the determination of the dimensional information from the characteristic values.

The device also represents a low-cost retrofitting option for existing systems, in particular, complicated medical imaging devices, e.g., a nuclear magnetic resonance tomography device or a computer tomography device. The invention not only improves the accuracy of the data delivered by existing devices, but can also universally utilized in a cost-effective fashion.

In one preferred embodiment of the invention, a characteristic value that is assigned to the interesting volume is also stored in the data memory such that the accuracy is additionally improved and physical and biological peculiarities can also be taken into consideration.

Characteristic values for each person operating the device may be alternatively or additionally stored in at least one data memory that is coupled to the means for determining the dimensional information. These characteristic values would make it possible to take into consideration the individual abilities of the respective persons during the segmenting process for determining the dimensional information and, in particular, an error interval assigned to the dimensional information. In this respect, it is advantageous to provide a data memory with test data records, on which the persons operating the device can carry out a manual or semi-automated test segmenting process in order to obtain reproducible and comparable information on the individual segmenting abilities. In this case, the evaluation of the test segmenting process, as well as the determination and storage of a personal

characteristic value for the respective person may also be realized automatically.

If it is - as deemed practical in numerous applications - planned to repeatedly test the individual segmenting abilities of the operating personnel within regular or irregular intervals, it is, according to the invention, possible to assign a data record to the individual characteristic values which identifies the test data record(s) used for determining the respective characteristic value. Due to this measure, it can be advantageously ensured that one and the same person receives a defined test data record during repeated test segmenting processes. For example, the test data record may contain test data that are repeatedly presented to this person so as to ascertain the error bandwidth of this person during the segmenting process. The test data record may also contain test data that is presented to the person only once or within longer intervals such that training effects caused by the frequent segmenting of identical test data and similar effects can also be determined. It would, for example, also be possible to respectively change only one or two or very few test data in a test data record for each new test segmenting process, with the remaining data not being changed.

In normal instances, it is practical to equip the device with means for illustrating and/or outputting the determined dimensional information and the determined error value. Monitors, printers, hard drives, CD-ROMs and diskettes may, in particular, be considered for this purpose.

The scope of the invention allows numerous modifications and additional developments that, for example, pertain to the type of characteristic values and their determination, as well as the measure for the error in the automatically

determined dimensional information which is derived thereof. In any case, it is essential to the invention that, when determining the volume, an error value for the dimensional information is determined and specified in addition to the dimensional information.

One possible embodiment of the invention is described below with reference to a semi-automated segmenting process which represents the most complex instance for realizing the present invention. In this case, one needs to differentiate between user-independent and user-dependent errors. In manual segmenting processes, only user-dependent errors are of decisive importance. Only user-independent errors are important in a fully automated segmenting process. However, both types of errors need to be taken into consideration in a semi-automated segmenting process.

One also needs to differentiate between independent and dependent errors. Independent errors in individual characteristic values can be assigned to a certain error source. These individual characteristic values can, for example, be incorporated into the calculation of the total error in the form of error information or in the form of a factor by means of error linking methods or simple multiplicative linking. However, it is known that dependent errors also occur, e.g., the signal-to-noise ratio and the tissue contrast. In this case, the dependence manifests itself with respect to the fact that, in semi-automated and manual segmenting processes, changes of these factors cause a change in the segmenting error which cannot be assigned to only one of the factors. The error caused by such dependent variables may, for example, be stored in a data memory in the form of a table. In this case, the number of dependent variables defines the dimensions of the table, and the table contains in each field a characteristic value or error value that corresponds to the corresponding columns of this table.

These characteristic values or error values are experimentally determined beforehand. This may, for example, be realized in the form of a large number of physicians carrying out test segmenting processes.

In order to determine the error during a concrete segmenting process, the actual values of the dependent variables, e.g., the signal-to-noise ratio and the tissue contrast, are initially determined. This may, for example, be realized in the form of an on-line calculation or a measurement. Subsequently, the errors corresponding to these variables are read out of the table. In this case, interpolations between individual fields of the table can be carried out depending on the respective requirements.

The thusly determined characteristic value or error value can subsequently be linked with independent characteristic values or error values in order to determine the total error. These independent characteristic values or error values may also be defined by a correlation between several variables. An algorithm-dependent error value for the algorithm used in the semi-automated segmenting process, as well as a user-dependent characteristic value or error value, may, in particular, be considered as such independent characteristic values or error values.

It is also possible to store a few or all dependent variables for each respective user. In this case, a predetermined table may, for example, be stored for each user. The accuracy of the error information increases proportionally with the number of variables that can be shifted from the user-independent table to the user-dependent table. In other respects, this has the disadvantage that the individual user or physician needs to segment a relatively large quantity of test data.

It should be emphasized that the method according to the invention and the device according to the invention do not correct measuring errors. The method according to the invention and the device according to the invention for the first time make it possible for an error that always occurs in methods and devices of this type to be incorporated into an evaluation of the measuring result to a relevant degree.

Other advantages, objectives and characteristics of the present invention are described below with reference to the figures that show the sequence of the method for determining a volume in an exemplary fashion. The individual figures show:

Figure 1 a flow chart of the sequence of a volume calculation, and

Figure 2 its chronological progression.

The embodiment shown in the figures is used for determining the volume of tumors, in particular, liver tumors, with a spiral-CT imaging device. A semi-automated segmenting algorithm is used for determining the volume. This means that a user-dependent and a user-independent influence on the accuracy of the volume measurement exist.

This also means that user-dependent and user-independent error components need to be taken into consideration as can be clearly ascertained from the two diagrams. The following parameters may, for example, be identified as influential factors: the size of the tumor as the object parameter, the contrast of the tumor as the imaging parameter and the segmenting algorithm used as the segmenting parameter.

In a first approximation, all remaining parameters can be considered to be constant. It goes without saying that

other parameters may also be considered influential and treated accordingly.

In order to determine a user-independent error, a test series is carried out with a spiral-CT under conventional abdomen imaging adjustments with the aid of a CT-phantom, namely with test objects of different sizes and different densities. The thusly obtained data are contoured with the aid of the related segmenting algorithm. In order to ensure that the result is not dependent on the user, the segmenting process is either carried out by a sufficiently large number of persons or repeated by one person to a sufficient degree. It goes without saying that the term "sufficient" is defined by a statistic convergence. A function f(x,y) that is two-dimensional in this case and describes the error in the volume measurement (f) in dependence on the object size (x) and the contrast (y) is derived from the thusly obtained volume data by mathematical manipulation.

In order to determine the user-dependent error, three representative test data records with clinical instances are chosen and segmented monthly by each user.

The results of these segmenting processes are stored. When the volume measuring system is used, the variability of all results is calculated online and the standard deviation is used as a measure for the user-dependent error. In this context, it would naturally also be possible to utilize other statistic processes for this purpose.

A total error function that is individually adapted to each user is achieved by linking the user-independent error and the user-dependent error - in case of doubt by means of corresponding known mathematical measures.

When the user subsequently carries out a volume measurement on a clinical data record, the error in the determination carried out on the clinical data record is estimated with the aid of the parameters contrast, size of the tumor and user influence. In this embodiment, the result is output in the form volume = xxx,xx ml +/- xx,xx ml. The progress of a therapy can be controlled much more precisely in this fashion because the user is also provided with information on the accuracy of the respective measurement. This is particularly important if, for example, the volume of the tumor apparently decreases during treatment while the corresponding error increases superproportionally, i.e., an increase in the volume of the tumor could occur due to the limited measuring accuracy. In such instances, appropriate measures for increasing the measuring accuracy would have to be carried out before the therapy can be deemed successful.

[Revised Page]

CLAIMS

1. A method for determining volumes in human bodies or animal bodies, wherein image data of an interesting volume are acquired by means of a suitable imaging method and the acquired image data are segmented in a manual, semi-automated or fully automated fashion, and wherein dimensional information on the interesting volume is automatically determined from the segmented image data, characterized by the fact

that at least one previously determined characteristic value is assigned to the steps in which the image data is acquired and segmented, with said characteristic value representing a measure for the error occurring in these steps, by the fact

that an error which represents a measure for the error occurring in the determination of the dimensional information is determined from the assigned characteristic value, and by the fact

that the error value is displayed or output, respectively, preferably together with the assigned dimensional information.

2. The method according to Claim 1, characterized by the fact that at least one characteristic value is also assigned to the interesting volume and taken into consideration when determining the error value of the dimensional information.

3. The method according to Claim 1 or 2, wherein the segmenting process is carried out in a manual or semi-

automated fashion, characterized by the fact that at least one ...

CLAIMS

1. A method for determining volumes in human bodies or animal bodies, wherein image data of an interesting volume are acquired by means of a suitable imaging method and the acquired image data are segmented in a manual, semi-automated or fully automated fashion, and wherein dimensional information on the interesting volume is automatically determined from the segmented image data, characterized by the fact

that at least one characteristic value is assigned to the steps in which the image data is acquired and segmented, with said characteristic value representing a measure for the error occurring in these steps, by the fact

that an error which represents a measure for the error occurring during the determination of the dimensional information is determined from the assigned characteristic value, and by the fact

that the error value is displayed or output, respectively, preferably together with the assigned dimensional information.

2. The method according to Claim 1, characterized by the fact that at least one characteristic value is also assigned to the interesting volume and taken into consideration when determining the error value of the dimensional information.

3. The method according to Claim 1 or 2, wherein the segmenting process is carried out in a manual or semi-automated fashion, characterized by the fact that at least one personal characteristic value is assigned to each person carrying out the method and taken into

consideration when determining the error value of the dimensional information.

4. The method according to Claim 3, characterized by the fact that the personal characteristic value assigned to each person is determined automatically.

5. The method according to Claim 4, characterized by the fact that the automatic determination of the characteristic value assigned to a person is realized based on a manual or semi-automated segmenting process which is carried out by the respective person with predetermined test data.

6. The method according to one of Claims 1 - 5, characterized by the fact that the at least one characteristic value assigned to the step in which the image data is acquired contains at least one measure from the following group of measures: signal-to-noise ratio, tissue contrast, pitch, increment, sequence parameters, layer thickness, matrix size, filter used.

7. The method according to one of Claims 1 - 6, wherein a semi-automated or automated segmenting process is carried out, characterized by the fact that the at least one characteristic value assigned to the step in which the segmenting is carried out contains a measure for the accuracy of a segmenting method used for the segmenting process and/or a measure for the reproducibility of the results of the segmenting method used.

8. The method according to Claim 2, characterized by the fact that the at least one characteristic value assigned to the interesting volume contains a measure for the size and/or the shape of the interesting volume.

9. The method according to one of Claims 1 - 8, characterized by the fact that the interesting volume consists of the volume of a tumor.

10. The method according to one of Claims 1 - 8, characterized by the fact that the interesting volume consists of the volume of an organ.

11. A device for determining volumes in human bodies or animal bodies, with means for inputting image data of an interesting volume, with means for segmenting the image data in a manual, semi-automated or fully automated fashion, and with means for automatically determining dimensional information on the interesting volume from the segmented image data, characterized by the fact

that at least one data memory is provided, by the fact

that characteristic values which can be assigned to the input and/or the segmented image data in accordance with predetermined criteria are stored in the at least one data memory, and by the fact

that the means for automatically determining the dimensional information are coupled to the at least one data memory and designed such

that they are able to read the characteristic values out of the data memory and determine an error value from the characteristic values which represents a measure for the error occurring in the determination of the dimensional information.

12. The device according to Claim 11, characterized by the fact that a characteristic value which is assigned to the interesting volume is stored in the data memory.

13. The device according to Claim 11 or 12, characterized by the fact that means are provided for displaying and/or outputting the determined dimensional information and the determined error value.

14. The device according to one of Claims 11 - 13, characterized by the fact that characteristic values for each person operating the device are stored in at least one data memory that is coupled with the means for determining the dimensional information.

15. The device according to Claim 14, characterized by the fact that a data memory with test data records is provided, wherein the person operating the device is able to carry out a manual or semi-automated test segmenting process on said test data records.

16. The device according to Claim 15, characterized by the fact that means are provided for evaluating the test segmenting process, as well as for determining and storing a personal characteristic value for the respective person.

17. The device according to Claim 16, characterized by the fact that a data record is assigned to the personal characteristic values, wherein said data record identifies the test data record/test data records used for determining the respective characteristic value.

18. A medical imaging apparatus with a device according to one of Claims 11 - 17.

19. A utilization of a device or a medical apparatus according to one of Claims 11 - 18 for determining the volume of a tumor.

20. The utilization of a device or medical apparatus according to one of Claims 11 - 18 for determining the volume of an organ.

ABSTRACT

In known methods and devices, image data of an interesting volume are acquired by means of a suitable imaging method, with the acquired image data being segmented in a manual, semi-automated or fully automated fashion, and with dimensional information on the interesting volume being automatically determined from the segmented image data.

In order to improve the usability of the automatically determined dimensional information, in particular, to increase its accuracy, at least one characteristic value is assigned to the steps in which the image data is acquired and segmented, with said characteristic value representing a measure for the error occurring in these steps. Subsequently, an error value is determined from the assigned characteristic value in the form of a measure for the error occurring in the determination of the dimensional information, and the error value is displayed or output, respectively.

Fig. 1

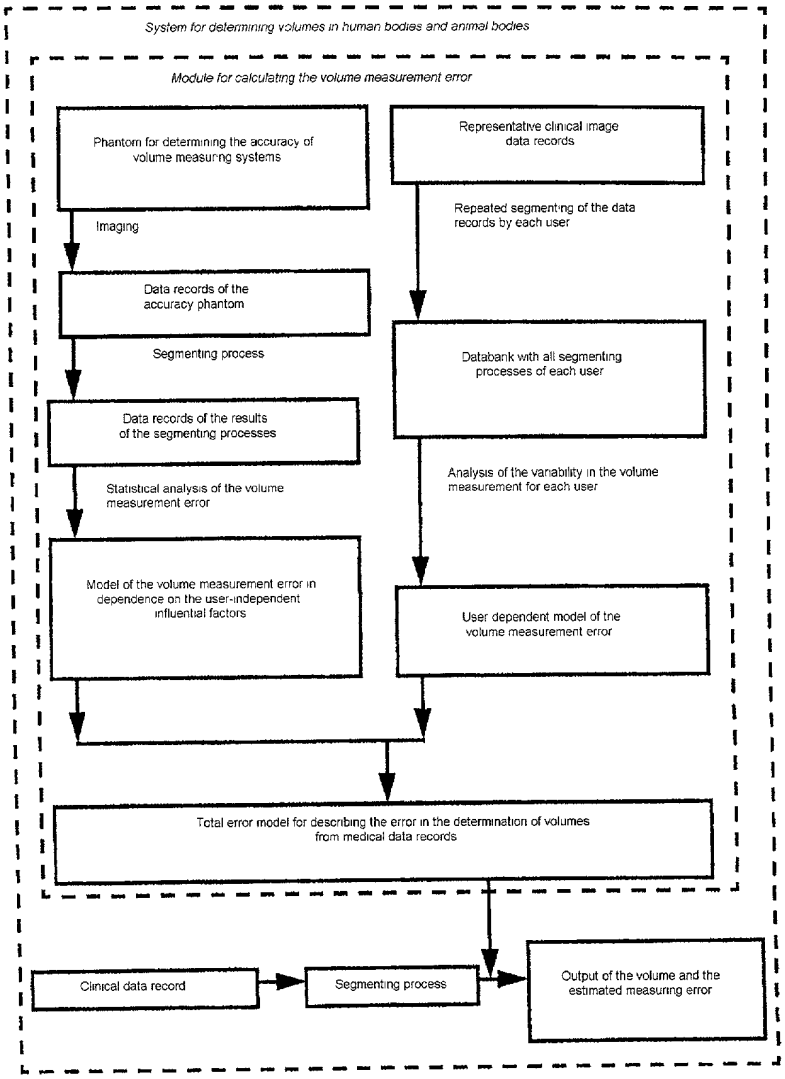
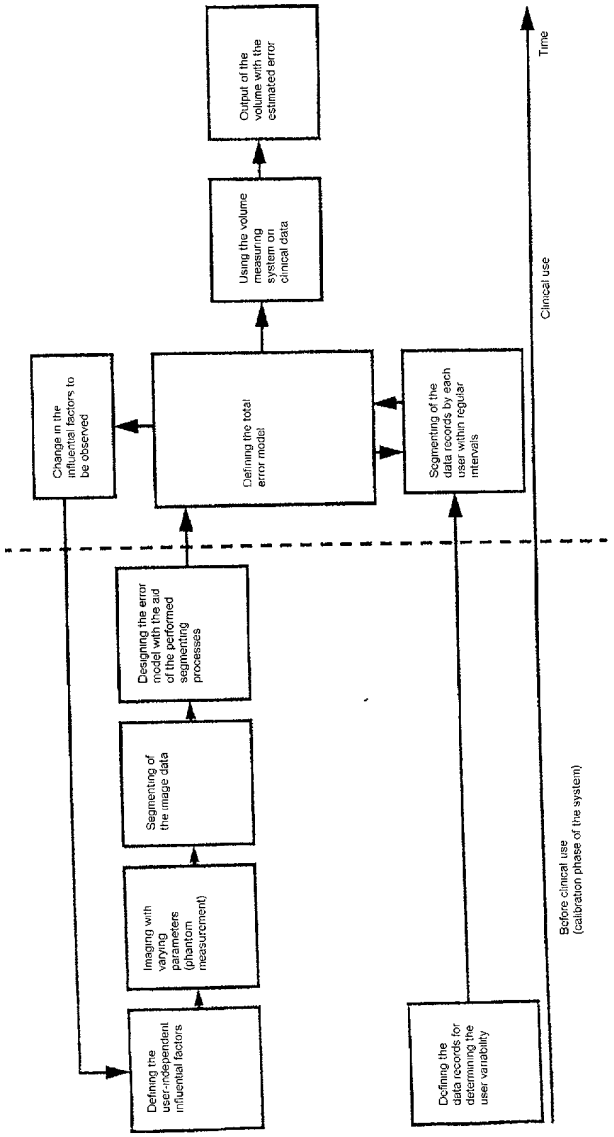

System for determining volumes in human bodies and animal bodies
Module for calculating the volume measurement error
Phantom for determining the accuracy of volume measuring systems
Representative clinical image data records
Imaging
Repeated segmenting of the data records by each user
Data records of the accuracy phantom
Segmenting process
Databank with all segmenting processes of each user
Data records of the results of the segmenting processes
Statistical analysis of the volume measurement error
Analysis of the variability in the volume measurement for each user
Model of the volume measurement error in dependence on the user-independent influential factors
User dependent model of the volume measurement error
Total error model for describing the error in the determination of volumes from medical data records
Clinical data record
Segmenting process
Output of the volume and the estimated measuring error

Fig. 2


Output of the volume with the estimated error
Using the volume measuring system on clinical data
Change in the influential factors to be observed
Defining the total error model
Segmenting of the data records by each user within regular intervals
Designing the error model with the aid of the performed segmenting processes
Segmenting of the image data
Imaging with varying parameters (phantom measurement)
Defining the user-independent influential factors
Defining the data records for determining the user variability
Time
Clinical use
Before clinical use
(calibration phase of the system)

Declaration and Power of Attorney for Patent Application
Erklärung für Patentanmeldungen mit Vollmacht
German Language Declaration

Als nachstehend benannter Erfinder erkläre ich hiermit an Eides statt:

As a below named inventor, I hereby declare that:

dass mein Wohnsitz, meine Postanschrift, und meine Staatsangehörigkeit den im Nachstehenden nach meinem Namen aufgeführten Angaben entsprechen.

My residence, post office address and citizenship are as stated below next to my name,

dass ich, nach bestem Wissen, der ursprüngliche, erste und alleinige Erfinder (falls nachstehend nur ein Name angegeben ist) oder ein ursprünglicher, erster und Miterfinder (falls nachstehend mehrere Namen aufgeführt sind) des Gegenstandes bin, für den dieser Antrag gestellt wird und für den ein Patent beantragt wird für die Erfindung mit dem Titel:

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

METHOD AND DEVICE FOR DETERMINING VOLUMINA IN THE HUMAN OR ANIMAL BODY

deren Beschreibung (Zutreffendes ankreuzen)

the specification of which (check one)

☑ hier beigefügt ist.

☑ is attached hereto.

☐ am _____ unter der Anmeldungsserienummer_____eingereicht wurde und am..... abgeändert wurde (falls tatsächlich abgeändert).

☑ was filed on July 6, 2001 as Application Serial No. 09/889,003 and was amended on (if applicable)

Ich bestätige hiermit, dass ich den Inhalt der obigen Patentanmeldung, einschließlich der Ansprüche, durchgesehen und verstanden habe, die eventuell durch einen Zusatzantrag wie oben erwähnt abgeändert wurde

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

Ich erkenne meine Pflicht zur Offenbarung irgendwelcher Informationen, die für die Prüfung der vorliegenden Anmeldung in Einklang mit Absatz 37, Bundesgesetzbuch, Paragraph 1.56(a) von Wichtigkeit sind, an.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

Ich beanspruche hiermit ausländische Prioritätsvorteile gemäss Abschnitt 35 der Zivilprozessordnung der Vereinigten Staaten, Paragraph 119, aller unten angegebenen Auslandsanmeldungen für ein Patent oder eine Erfinderurkunde, und habe auch alle Auslandsanmeldungen für ein Patent oder eine Erfinderurkunde nachstehend gekennzeichnet, die ein Anmeldedatum haben, das vor dem Anmeldedatum der Anmeldung liegt, für die Priorität beansprucht wird.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

German Language Declaration

Prior foreign applications Vorherige Anmeldungen			Priority Claimed Priorität beansprucht	
(Number) (Nummer)	(Country) (Land)	(Day/Month/Year Filed) (Tag/Monat/Jahr eingereicht)	Yes Ja	No Nein
199 00 414.5	Deutschland	08. Januar 1999	Ja	
	Germany	January 8, 1999	Yes	

Ich beanspruche hiermit gemäss Absatz 35 der Zivilprozessordnung der Vereinigten Staaten, Paragraph 120, den Vorzug aller unten aufgeführten Anmeldungen, und falls der Gegenstand aus jedem Anspruch dieser Anmeldung nicht in einer früheren amerikanischen Patentanmeldung laut dem ersten Paragraphen des Absatzes 35 der Zivilprozessordnung der Vereinigten Staaten, Paragraph 112 offenbart ist, erkenne ich gemäss Absatz 37, Bundesgesetzbuch, Paragraph 1.56(a), meine Pflicht zur Offenbarung von Informationen an, die zwischen dem Anmeldedatum der früheren Anmeldung und dem nationalen oder PCT internationalen Anmeldedatum dieser Anmeldung bekannt geworden sind.

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations,§1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PCT/DE00/00038 (Application Serial No.) (Anmeldeseriennummer)	January 5, 2000 (Filing Date) (Anmeldedatum)	(Status) (patentiert, anhängig, aufgegeben	(Status) (patented, pending, abandoned)
(Application Serial No.) (Anmeldeseriennummer)	(Filing Date) (Anmeldedatum)	(Status) (patentiert, anhängig, aufgegeben	(Status) (patented, pending, abandoned)

Ich erkläre hiermit, dass alle von mir in der vorliegenden Erklärung gemachten Angaben nach meinem besten Wissen und Gewissen der vollen Wahrheit entsprechen, und dass ich diese eidesstattliche Erklärung in Kenntnis dessen abgebe, dass wissentlich und vorsätzlich falsche Angaben gemäss Paragraph 1001, Absatz 18 der Zivilprozessordnung der Vereinigten Staaten von Amerika mit Geldstrafe belegt und/oder Gefängnis bestraft werden können, und dass derartig wissentlich und vorsätzlich falsche Angaben die Gültigkeit der vorliegenden Patentanmeldung oder eines darauf erteilten Patentes gefährden können.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

German Language Declaration

VERTRETUNGSVOLLMACHT: Als benannter Erfinder beauftrage ich hiermit den nachstehend benannten Patentanwalt (oder die nachstehend benannten Patentanwälte) und/oder Patent-Agenten mit der Verfolgung der vorliegenden Patentanmeldung sowie mit der Abwicklung aller damit verbundenen Geschäfte vor dem Patent- und Markenamt:

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

STEVEN J. HULTQUIST, Registration No. 28021
MARIANNE FUIERER, Registration No. 39983
WILLIAM A. BARRETT, Registration No. 42296

Telefongespräche bitte richten an:
(919) 419-9350
Postanschrift:
Steven J. Hultquist
Intellectual Property/Technology Law
P.O. Box 14329
Research Triangle Park, NC 27709

Direct Telephone call to:
(919) 419-9350
Send Correspondence to:
Steven J. Hultquist
Intellectual Property/Technology Law
P.O. Box 14329
Research Triangle Park, NC 27709

Full name of the first inventor Voller Name des ursprünglichen Erfinders	Residence Wohnsitz	Citizenship Staatsangeh.	Post Office Address Postanschrift	Inventor's Signature Unterschrift des Erfinders	Date Datum
Malte Bahner	Germany	Germany	Karlstr. 9 67117 Heidelberg		7/24/01
Full name of additional or joint inventor Voller Name des Miterfinders	**Residence Wohnsitz**	**Citizenship Staatsangeh.**	**Post Office Address Postanschrift**	**Inventor's Signature Unterschrift des Erfinders**	**Date Datum**
Andreas Mahr	Germany	Germany	Christophstr. 12 69214 Eppelheim		20.7.2001
Sabine Levegrün	U.S.A.	Germany.	504 East 63rd, App. 4M 10021 New York	S. levegrün	20.7.01